Remarks

The specification has been amended to remove hyperlinks and browser executable code. Claims 4-7 have been cancelled without prejudice to or disclaimer of the underlying subject matter. Claim 3 has been amended in the present Response to Office Action as well as in the Amendment and Reply to Restriction Requirement previously filed on January 13, 2003. Support for this amendment can be found throughout the specification, for example, at page 1, line 20, and the claims as originally filed. New claims 8-11 have been added. Support for the new claims can be found throughout the specification as originally filed, for example, at page 19 line 23 to page 20 line 12. No new matter enters by these amendments.

I. Status

The Examiner indicated on the Office Action Summary Sheet that this office action is responsive to the communication filed on November 19, 2002. Applicants note that the most recent communication was filed on January 13, 2003 in response to an office action mailed December 18, 2002. During a telephone conference with the Examiner on April 27, 2003, the Examiner indicated that he did not receive the January 13, 2003 communication and requested that we submit a copy with this Response. Accordingly, Applicants enclose herewith a copy of the communication previously submitted on January 13, 2003. Applicants further respectfully request that the Examiner inform Applicants whether or not the claim amendment and request for withdrawal of the restriction requirement submitted in the January 13, 2003 communication are accepted.

II. Rejection under 35 U.S.C. §112, 1st Paragraph, Written Description

Claims 2-7 stand rejected under 35 U.S.C. § 112, first paragraph, for allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Office Action at page 2. Applicants respectfully disagree.

The Examiner asserts that Applicants' arguments filed on November 19, 2002 are not persuasive "because only SEQ ID NO: 1, but not the full breadth of the claim meet the written description provision of 35 U.S.C. 112, first paragraph." Office Action at page 5.

Applicants reiterate that the purpose of the written description requirement is to ensure that the inventors had possession of the claimed subject matter, *i.e.*, to ensure that the inventors actually invented what is claimed. *Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172, 37 U.S.P.Q.2d 1578, 1581 (Fed. Cir. 1996). In accordance with this purpose, Applicants need not "describe," in the sense of Section 112, all things that are encompassed by the claims. To contend otherwise would contradict established jurisprudence, which teaches that a patent may be infringed by technology developed after a patent issues. *United States Steel Corp. v. Phillips Petroleum Co.*, 865 F.2d 1247, 1251, 9 U.S.P.Q.2d 1461, 1464 (Fed. Cir. 1989). A related, and equally well-established principle of patent law is that claims "may be broader than the specific embodiment disclosed in a specification." *Ralston Purina Co. v. Far-mor-Co*, 772 F.2d 1570,

1575, 227 U.S.P.Q. 177, 179 (Fed. Cir. 1985), *quoting In re Rasmussen*, 650 F.2d 1212, 1215, 211 U.S.P.Q. 323, 326 (C.C.P.A. 1981). Thus, in order for Applicants to describe each and every molecule encompassed by the claims, it is not required that every aspect of those nucleic acid molecules be disclosed. *In re Alton,* 76 F.3d 1168, 1175, 37 U.S.P.Q.2d 1578, 1581 (Fed. Cir. 1996) (a person of ordinary skill in the art would have understood the inventor to have been in possession of the claimed invention at the time of filing even if every nuance of the claims is not explicitly described in the specification).

Applicants thank the Examiner for the acknowledgement that SEQ ID NO: 1 meets the written description requirement. However, the Examiner contends that the full breadth of the claims does not meet the written description requirement. Office Action at page 5. The Examiner seems to assert that proper written description support for a claim directed to a nucleic acid sequence requires nothing less than the actual disclosure of every sequence encompassed by that claim. In support of these propositions, the Examiner relies on *Regents of the University of California v. Eli Lilly and Co*, 119 F.3d 1559, 43 U.S.P.Q.2d 1398 (Fed. Cir. 1997). Applicants respectfully disagree. In *Eli Lilly* the court found that claims to a vertebrate cDNA coding for insulin were inadequately described. However, the present case is clearly different from *Eli Lilly*. Specifically, the present claims "distinguish the claimed genus from others" and define "structural features commonly possessed by members of the genus that distinguishes them from others," unlike the claims at issue in *Eli Lilly*. *Id.* at 1568-69.

Further, in *Moba B.V. v. Diamond Automation, Inc.*, -- F.3d --, 2003 WL 1701374, 10 (Fed. Cir. 2003), the Federal Circuit clarified that a "court should determine whether a person of

skill in the art would glean from the written description, including information obtainable from the deposits of the claimed sequences, subsequences, mutated variants and mixtures sufficient to demonstrate possession of the generic scope of the claims." *Moba* at 10, *citing Enzo Biochem, Inc. v. Gen-Probe, Inc.* 296 F.3d 1316, 1328, 63 U.P.Q.2d 1609 (Fed. Cir. 2002). The Federal Circuit also reiterated that "[t]he test for compliance with §112 has always required sufficient information in the original disclosure to show that the inventor possessed the invention at the time of the original filling." *Moba* at 10.

The Court further states that the "written description requirement does not require the applicant 'to describe exactly the subject matter claimed, [instead] the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.'" *Moba* at 10, *citing Union Oil Co. of Cal. v. Atlantic Richfield Co.,* 208 F.3d 989, 997, 54 U.S.P.Q.2d 1227, 1232 (Fed. Cir. 2000). Finally, the Court explained that "the *Lilly* disclosure rule does not require a particular form of disclosure because one of skill could determine from the specification that the inventor possessed the invention at the time of filing." *Moba* at 10.

The Examiner admits that "[a]n adequate written description of a DNA,...'requires a precise definition, such as by structure, formula, chemical name, or physical properties.'" Office Action at page 4, *citing Fiers v. Revel*, 984 F.2d 1161, 1171, 25 U.S.P.Q.2d 1601, 1606 (Fed. Cir. 1993). However, the Examiner provides no explanation for the proposition that Applicants have not satisfied this requirement for written description. In particular, Applicants have provided a detailed chemical structure (SEQ ID NO: 1) that distinguishes that claimed genus from other nucleic acid molecules. Moreover, nucleic acid molecules falling within the scope of

the present claims are readily identifiable in that they comprise a nucleic acid molecule having the sequence of SEQ ID NO: 1 and complements thereof. The fact that the nucleic acid molecules may comprise additional sequences or variations is beside the point. Such modifications are readily envisioned by one of ordinary skill in the art and disclosed through the present specification, for example, as site directed mutagenesis, microsatellites or other markers. *See, e.g.*, specification at page 20, line 16 through page 21, line 20 and at page 59, line 11 through page 60, line 27.

Thus, one of ordinary skill in the art would recognize that Applicants had possession of the claimed genus of nucleic acid molecules in light of the present disclosure. Accordingly, for all of the foregoing reasons, there is no deficiency in the written description support for claims 2-7 under 35 U.S.C. § 112, first paragraph. Reconsideration and withdrawal of this rejection are respectfully requested.

III. Rejection under 35 U.S.C. §112, 2nd Paragraph, Indefiniteness

Claims 3-7 stand rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite "for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention." Office Action at page 5. Claims 3-7 are rejected over the recitation of the phrase "consisting essentially of."

Applicants respectfully disagree; however, in Applicants' response to the December 18, 2002 Office Action, Applicants amended claim 3. Amended claim 3 does not contain the phrase "consisting essentially of." The Examiner's rejection is therefore moot. Withdrawal of this rejection is respectfully requested.

IV. Claim Objections

The Examiner has objected to claims 4-7 under 37 CFR 1.75(c) as allegedly being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicants respectfully disagree; however, in order to facilitate prosecution, claims 4-7 have been cancelled. Reconsideration and withdrawal of this objection are respectfully requested.

V. Specification

The disclosure is objected to because it allegedly contains an embedded hyperlink and/or other form of browser-executable code on page numbers 5, 8, 9, 90, and 91 of the specification. Office Action at page 6. Applicants have amended the specification to remove "http://" and embedded hyperlinks on pages 8, 9, 90, and 91 of the specification. The website addresses on page 5 of the disclosure, described by the Examiner as containing embedded hyperlink and /or other forms of browser executable code, do not contain such browser-executable code as specified in MPEP § 608.01 (d). According to MPEP § 608.01 (d), "examples of a hyperlink or browser-executable code are a URL placed between these symbols '< >' and 'http://' followed by a URL address." (MPEP Volume 7-1). However, to facilitate prosecution, Applicants have replaced "ftp.ebi.ac.uk" with "ftp-ebi.ac.uk" and have replaced "ncbi.nlm.nih.gov" with "ncbi-nlm.nih.gov" on page 5.

Applicants contend that the URL addresses themselves contained throughout the specification do not constitute browser-executable code in the absence of embedded hyperlinks and/or other forms of browser-executable code. *See* MPEP, § 608.01 (d). Accordingly, Applicants respectfully request that the Examiner withdraw the objection.

VI. Rejection under 35 U.S.C. 101

Claims 1-7 stand rejected under 35 U.S.C. 101 because the claimed invention allegedly lacks patentable utility due to not being supported by either specific and/or substantial utility or a well established utility. Office Action at page 6. Applicants respectfully disagree and traverse this rejection.

The Examiner acknowledges that the specification describes multiple utilities for the present invention, including "probes for assisting in the isolation of full-length cDNAs or genes which would be used to make protein and optionally further usage to make the corresponding antibodies, gene mapping, isolation of homologous sequences, detection of gene expression such as in Northern blot analysis, molecular weight markers, chromosomal markers, for numerous other generic genetic engineering usages, expression, antibody production, Western blots, etc." Office Action at page 7. However, the Examiner contends that these utilities are "non-specific uses that are applicable to nucleic acid(s) and/or proteins in general and not particular or specific to the nucleic acid(s) being claimed." Office Action at page 7. Applicants respectfully disagree with this assertion.

It is well established that "when a properly claimed invention meets at least one stated objective, utility under section 101 is clearly shown." *Raytheon Co. v. Roper Corp.,* 724 F.2d 951, 958, 220 U.S.P.Q. 592, 298 (Fed. Cir. 1983). The present specification describes many objectives that are met by the present invention. In addition to the utilities described by the Examiner (quoted above), the claimed nucleic acid molecules are useful for obtaining nucleic acid molecules that encode for other isozymes or gene family members, acquiring molecular

markers, constructing linkage maps, acquiring promoters and transcriptional regulatory elements, site directed mutagenesis, transformation, etc. *See, e.g.*, page 39 under "Uses of the Agents of the Invention."

Many of these uses are directly analogous to the use of a microscope. An important utility of a microscope resides in its use to identify and characterize the structure of biological tissues in a sample, cell or organism. Significantly, the utility of the microscope under 35 U.S.C. § 101 is not compromised by its use as a tool in this manner. Many of the presently disclosed utilities are directly analogous to the utilities of a microscope, *i.e.*, the claimed nucleic acid molecules may be used to identify and characterize other nucleic acid molecules within a sample, cell or organism. Such utility is indistinguishable from the legally sufficient utility of a microscope. Thus, the presently disclosed sequences possess the requisite utility under 35 U.S.C. § 101.

In the Office Action, the Examiner provides no evidence challenging the disclosed utilities for the presently claimed nucleic acid molecules. Rather the Examiner attempts to undermine the existing utilities by stating that they "are non-specific uses that are applicable to nucleic acid(s) and/or proteins in general and not particular or specific to the nucleic acid(s) and/or protein(s) being claimed" Office Action at page 7. In short, the Examiner suggests that the asserted utilities are legally insufficient simply because other molecules can be used for the same purpose. This position is wrong as a matter of law – there is no requirement of exclusive utility in the patent law. *See Carl Zeiss Stifung v. Renishaw PLC*, 945 F.2d 1173, 1180, 20

U.S.P.Q.2d 1094, 1100 (Fed. Cir. 1991) ("An invention need not be the best or the only way to accomplish a certain result...").

Moreover, this position offends the sensibilities. For example, such an argument implies that a new golf club has no legal utility because other golf clubs can be used for the same purpose, *i.e.,* hitting golf balls. Such a result is not only untenable, but requires reading "into the patent laws limitations and conditions which the legislature has not expressed," a practice condemned by the Supreme Court. *See Diamond v. Chakrabarty*, 447 U.S. 303, 308, 306 U.S.P.Q. 193, 196 (1980), *quoting United States v. Dubilier Condenser Corp.,* 289 U.S. 178, 199, 17 U.S.P.Q. 154, 163 (1933). Thus, it must be the case that a utility, generic to a broad class of molecules, does not compromise the specific utility of an individual member of that class.

As noted above, the claimed nucleic acid molecules have many utilities. Some of these utilities may be common to a broader class of molecules. For instance, nucleic acid sequences may generally be used to identify and locate related sequences. However, when used in this manner, the result is not generic. Rather, the claimed nucleic acid molecules will identify a ***unique*** subset of related sequences. This subset of related sequences is specific to the claimed sequences and cannot be identified by any generic nucleic acid molecule. For example, a random nucleic acid molecule would not provide this specific utility. Referring again to the golf club analogy, the club is still generically hitting a golf ball, but is uniquely designed to hit a ball in a manner that is distinct from other clubs. Once again, Applicants assert that the claimed nucleic acid molecules exhibit the requisite utility under 35 U.S.C. § 101.

The Examiner also states that the credibility of the presently asserted utilities has not been established. Office Action at page 8. Credibility is precisely the issue that the courts have emphasized in evaluating the adequacy of an asserted utility. Utility is determined "by reference to, and a factual analysis of, the disclosure of the application." *In re Ziegler*, 992 F.2d 1197, 1201, 26 U.S.P.Q.2d 1600, 1603 (Fed. Cir. 1993), *quoting Cross v. Iizuka*, 752 F.2d 1040, 1044, 224 U.S.P.Q. 739, 742 (Fed. Cir. 1985). The Examiner "has the initial burden of challenging a presumptively correct assertion of utility in the disclosure." *In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). The utilities asserted in the specification must be accepted as factually sound unless the Patent Office cites information that undermines the credibility of the assertion. *Id.* The Examiner "must do more than merely question – [he] must set forth factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability." *In re Gaubert*, 524 F.2d 1222, 1225-26, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975) (emphasis in original); MPEP § 706.03(a)(1) ("Office personnel are reminded that they must treat as true a statement of fact made by an applicant in relation to an asserted utility, unless countervailing evidence can be provided..."). Here the Examiner has not even attempted to meet this burden. Thus, the Examiner's admission that the credibility of the disclosed utilities is not challenged is tantamount to an admission that no proper rejection has been made.

In view of the above, Applicants contend that the claimed nucleic acid molecules are supported by credible, specific and substantial utilities disclosed in the specification. Moreover, the Examiner has failed to raise any credible evidence challenging the presently asserted utilities.

Consequently, the rejection is improper. Reconsideration and withdrawal of this rejection are respectfully requested.

VII. Rejection under 35 U.S.C. §112, 1st Paragraph, Written Description

Claims 1-7 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to meet the written description requirement. Office Action at page 9. Specifically, the Examiner claims that since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility, one skilled in the art would not know how to use the claimed invention. This rejection has been overcome by the arguments regarding utility above. Consequently, withdrawal of this rejection is respectfully requested.

VIII. Rejection under 35 U.S.C. §102

Claims 3-7 stand rejected under 35 U.S.C. §102(a) as allegedly being anticipated by The Sanger Center and The Washington University Genome Sequencing Center (Genome Research, (1998) Vol. 8, pages 1097-1108). Office Action at page 9. Applicants respectfully disagree. The Examiner states that the rejection is based on the phrase "consisting essentially of." However, this phrase was removed from claim 3 in the Amendment filed on January 13, 2003. Consequently, this rejection has been rendered moot by the foregoing claim amendments and withdrawal of this rejection is respectfully requested.

In view of the above, the presently pending claims are believed to be in condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding

rejections and pass the application to issue. The Examiner is encouraged to contact the undersigned with respect to any unresolved issues remaining in this application.

Respectfully submitted,

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